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INFORMATION DISCLOSURE  
STATEMENT  
Examining Group 1638  
Patent Application  
Docket No. CHL-T107C3Z1  
Serial No. 10/500,351

  
Jeff Lloyd, Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Unit : 1638  
Applicant : Henry Daniell  
Serial No. : 10/500,351  
Filed : June 25, 2004  
Conf. No. : 2622  
For : Expression of Antigens in Chloroplasts for Production of Improved Vaccines

Mail Stop Amendment  
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INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§1.97 AND 1.98

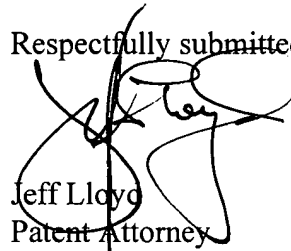
Sir:

The above-identified patent application was filed in the U.S. Patent Office as a national application under 35 USC §371. Applicant has been notified that a copy of the International Search Report has been made available in the national stage file as indicated on the Notice of Acceptance of the Application Under 35 USC 371 (Form PCT/DO/EO/903). The Notice does not indicate whether copies of the references cited in the International Search Report were received by the Patent Office. Therefore, copies of the references cited in the International Search Report are enclosed for the Examiner's convenience. In accordance with 37 CFR §1.56, Applicant hereby requests that the references cited in the International Search Report and listed on the attached form PTO/SB/08 be made of record and considered in the examination of the subject application.

Applicant has also listed on form PTO/SB/08 numerous references which have not been cited in the international search report. Copies of these documents are enclosed with this IDS. Applicant respectfully requests that these references be made of record and considered in the examination of the subject application.

Applicant respectfully asserts that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,



Jeff Lloyd

Patent Attorney

Registration No. 35,589

Phone No.: 352-375-8100

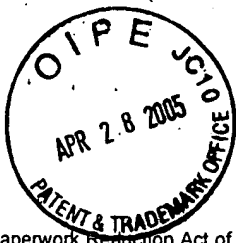
Fax No.: 352-372-5800

Address: P.O. Box 142950

Gainesville, FL 32614-2950

JL/amh

Attachment: Form PTO/SB/08; copies of cited references.



PTO/SB/08A (08-03)  
Approved for use through 07/31/2006. OMB 0651-0031  
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				Application Number	10/500,351
				Filing Date	June 25, 2004
				First Named Inventor	Henry Daniell
				Art Unit	1638
				Examiner Name	
Sheet	1	of	12	Attorney Docket Number	CHL-T107C3Z1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	U1	US-			
	U2	US-			
	U3	US-			
	U4	US-			
	U5	US-			
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	U8	US-			
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FOREIGN PATENT DOCUMENTS						
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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	F1	WO 00/03022 A3	01/20/2000	CALGENE LLC	ALL	
	F2	WO 01/72959 A2 (CD-ROM)	10/04/2001	AUBURN UNIVERSITY	ALL	
	F3	WO 99/10513 A1 (CD-ROM)	03/04/1999	AUBURN UNIVERSITY	ALL	
	F4					
	F5					
	F6					
	F7					

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	R1	AHUJA, N. <i>et al.</i> "Rapid Purification of Recombinant Anthrax-Protective Antigen under Nondenaturing Conditions" <i>Biochemical and Biophysical Research Communications</i> , 2001, pp. 6-11, Vol. 286.	
	R2	ALTPETER, F. <i>et al.</i> "Generation Of Large Numbers Of Independently Transformed Fertile Perennial Ryegrass ( <i>Lolium perenne</i> L.) Plants Of Forage- And Turf Type Cultivars" <i>Mol. Breeding</i> , 2000, pp. 519-528, Vol. 6.	
	R3	ALTPETER, F. <i>et al.</i> "Integration And Expression Of The High-Molecular-Weight Glutelin Subunit 1Ax1 Gene Into Wheat" <i>Nat. Biotechnol.</i> , September 1996, pp. 1155-1159, Vol. 14, No. 9.	
	R4	ANDERSON, G. W. JR. <i>et al.</i> "Recombinant V Antigen Protects Mice against Pneumonic and Bubonic Plague Caused by F1-Capsule-Positive and -Negative Strains of <i>Yersinia pestis</i> " <i>Infection and Immunity</i> , November 1996, pp. 4580-4585, Vol. 64, No. 11.	
	R5	ANDREWS, G. P. <i>et al.</i> "Protective Efficacy of Recombinant <i>Yersinia</i> Outer Proteins against Bubonic Plague Caused by Encapsulated and Nonencapsulated <i>Yersinia pestis</i> " <i>Infection and Immunity</i> , March 1999, pp. 1533-1537, Vol. 67, No. 3.	
	R6	ARAKAWA, T. <i>et al.</i> "Expression of cholera toxin B subunit oligomers in transgenic potato plants" <i>Transgenic Research</i> , 1997, pp. 403-413, Vol. 6.	
	R7	BAILLIE, L. "The development of new vaccines against <i>Bacillus anthracis</i> " <i>Journal of Applied Microbiology</i> , 2001, pp. 609-613, Vol. 91.	
	R8	BECK L. R. <i>et al.</i> "A new long-acting injectable microcapsule system for the administration of progesterone" May 1979, pp. 545-551, Vol. 31, No. 5.	
	R9	BELIAKOV, I. M. <i>et al.</i> "Interplay of Cytokines and Adjuvants in the Regulation of Mucosal and Systemic HIV-Specific CTL" <i>The Journal of Immunology</i> , 2000, pp. 6454-6462, Vol. 165.	
	R10	BERNEMAN, A. <i>et al.</i> "The Specificity Patterns of Human Immunoglobulin G Antibodies in Serum Differ from Those in Autologous Secretions" <i>Infection and Immunity</i> , September 1998, pp. 4163-4168, Vol. 66, No. 9.	
	R11	BHATNAGAR, R. <i>et al.</i> "Calcium Is Required for the Expression of Anthrax Lethal Toxin Activity in the Macrophagelike Cell Line J774A.1" <i>Infection and Immunity</i> , July 1989, pp. 2107-2114, Vol. 57, No. 7.	
	R12	BOCCI, V. "The Oropharyngeal Delivery of Interferons: Where Are We and Where Do We Need to Go?" <i>Journal of Interferon and Cytokine Research</i> , 1999, pp. 859-861, Vol. 19.	

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Sheet	3	of	12	Attorney Docket Number	CHL-T107C3Z1

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	R13	BOCKMAN DE <i>et al.</i> "Pinocytosis by epithelium associated with lymphoid follicles in the bursa of Fabricius, appendix, and Peyer's patches. An electron microscopic study" <i>American Journal of Anatomy</i> , April 1973, pp. 455-477, Vol. 136, No. 4.	
	R14	BOUVET, J. P. <i>et al.</i> "Stimulation of local antibody production: parenteral or mucosal vaccination?" <i>Trends in Immunology</i> , April 2002, pp. 209-213, Vol. 23, No. 4.	
	R15	BOUVET, J. P. <i>et al.</i> "Diversity of Antibody-Mediated Immunity at the Mucosal Barrier" <i>Infection and Immunity</i> , June 1999, pp. 2687-2691, Vol. 67, No. 6.	
	R16	BRADLEY, K. A. <i>et al.</i> "Identification of the cellular receptor for anthrax toxin" <i>Nature</i> , November 8, 2001, pp. 225-229, Vol. 414.	
	R17	BROSSIER, F. <i>et al.</i> "Role of Toxin Functional Domains in Anthrax Pathogenesis" <i>Infection and Immunity</i> , April 2000, pp. 1781-1786, Vol. 68, No. 4.	
	R18	CÁRDENAS-FREYTAG, L. <i>et al.</i> "Effectiveness of a Vaccine Composed of Heat-Killed <i>Candida albicans</i> and a Novel Mucosal Adjuvant, LT(R192G), against Systemic Candidiasis" <i>Infection and Immunity</i> , February 1999, pp. 826-833, Vol. 67, No. 2.	
	R19	CASTAÑÓN, S. <i>et al.</i> "Immunization with Potato Plants Expressing VP60 Protein Protects against Rabbit Hemorrhagic Disease Virus" <i>Journal of Virology</i> , May 1999, pp. 4452-4455, Vol. 73, No. 5.	
	R20	CHAUHAN, V. <i>et al.</i> "Constitutive Expression of Protective Antigen Gene of <i>Bacillus anthracis</i> in <i>Escherichia coli</i> " <i>Biochemical and Biophysical Research Communications</i> , 2001, pp. 308-315, Vol. 283.	
	R21	CHO, M.-J. <i>et al.</i> "Production Of Transgenic Tall Fescue And Red Fescue Plants By Particle Bombardment Of Mature Seed-Derived Highly Regenerative Tissues" <i>Plant Cell Rep.</i> 2000, pp. 1084-1089.	
	R22	CHOI, A. H. C. <i>et al.</i> "Antibody-Independent Protection against Rotavirus Infection of Mice Stimulated by Intranasal Immunization with Chimeric VP4 or VP6 Protein" <i>Journal of Virology</i> , September 1999, pp. 7574-7581, Vol. 73, No. 9.	
	R23	CHOI, A. H. C. <i>et al.</i> "Functional Mapping of Protective Domains and Epitopes in the Rotavirus VP6 Protein" <i>Journal of Virology</i> , December 2000, pp. 11574-11580, Vol. 74, No. 24.	
	R24	CHONG C. <i>et al.</i> "LT(R192G), a non-toxic mutant of the heat-labile enterotoxin of <i>Escherichia coli</i> , elicits enhanced humoral and cellular immune responses associated with protection against lethal oral challenge with <i>Salmonella</i> spp." <i>Vaccine</i> , 1998, pp. 732-740, Vol. 16, No. 7.	

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Sheet	4	of	12	Attorney Docket Number	CHL-T107C3Z1

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	R25	COULSON, N. M. <i>et al.</i> "Bacillus anthracis protective antigen, expressed in Salmonella typhimurium SL 3261, affords protection against anthrax spore challenge" <i>Vaccine</i> , November 1994, pp. 1395-1401, Vol. 12, No. 15.	
	R26	CRAMER, C. L. <i>et al.</i> "Transgenic plants for therapeutic proteins: linking upstream and downstream strategies" <i>Current Topics Microbiol. Immunol.</i> , 1999, pp. 95-118, Vol. 240.	
	R27	CUMMINS, J. M. <i>et al.</i> "Oral Use of Interferon" <i>Journal of Interferon and Cytokine Research</i> , 1999, pp. 853-857, Vol. 19.	
	R28	DANIELL, H. "Foreign gene expression in chloroplasts of higher plants mediated by tungsten particle bombardment" <i>Methods Enzymol.</i> , 1993, pp. 536-556, Vol. 217.	
	R29	DANIELL, H. "Transformation and foreign gene expression in plants by microprojectile bombardment" <i>Methods Mol. Biol.</i> , 1997, pp. 463-489, Vol. 62.	
	R30	DANIELL, H. <i>et al.</i> "Containment of herbicide resistance through genetic engineering of the chloroplast genome" <i>Nature Biotechnology</i> , April 1998, pp. 345-348, Vol. 16, No. 4.	
	R31	DANIELL, H. <i>et al.</i> "Milestones in chloroplast genetic engineering: an environmentally friendly era in biotechnology" <i>Trends in Plant Science</i> , February 2002, pp. 84-91, Vol. 7, No. 2.	
	R32	DANIELL, H. <i>et al.</i> "Expression of the Native Cholera Toxin B Subunit Gene and Assembly as Functional Oligomers in Transgenic Tobacco Chloroplasts" <i>Journal of Mol. Biol.</i> , 2001, pp. 1001-1009, Vol. 311.	
	R33	DANIELL, H. <i>et al.</i> "Marker free transgenic plants: engineering the chloroplast genome without the use of antibiotic selection" <i>Curr. Genet.</i> , 2001, pp. 109-116, Vol. 39.	
	R34	DANIELL, H. <i>et al.</i> "Medical molecular farming: production of antibodies, biopharmaceuticals and edible vaccines in plants" <i>Trends in Plant Science</i> , May 2001, pp. 219-226, Vol. 6, No. 5.	
	R35	DANIELL, H. <i>et al.</i> "An efficient and prolonged in vitro translational system from isolated cucumber etioplasts" <i>Biochem. Biophys. Res. Commun.</i> , February 26, 1986, pp. 248-255, Vol. 135, No. 1.	
	R36	DANIELL, H. <i>et al.</i> "Uptake and expression of bacterial and cyanobacterial genes by isolated cucumber etioplasts" <i>Proc. Natl. Acad. Sci. USA</i> , September 1987, pp. 6349-6353, Vol. 84.	

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	R37	DANIELL, H. <i>et al.</i> "In vitro synthesis of photosynthetic membranes: I. Development photosystem I activity and cyclic photophosphorylation" <i>Biochem. Biophys. Res. Commun.</i> , March 16, 1983, pp. 740-749, Vol. 111, No. 2.	
	R38	DANIELL, H. <i>et al.</i> "Transient foreign gene expression in chloroplasts of cultured tobacco cells after biolistic delivery of chloroplast vectors" <i>Proc. Natl. Acad. Sci. USA</i> , January 1990, Vol. 87, No. 1.	
	R39	DANIELL, H. "Molecular strategies for gene containment in transgenic crops" <i>Nature Biotechnology</i> , June 2002, pp. 581-586, Vol. 20.	
	R40	DANIELL, H. <i>et al.</i> "Chloroplast culture. IX. Chlorophyll(ide) a biosynthesis in vitro rates higher than in vivo" <i>Biochem. Biophys. Res. Commun.</i> , May 31, 1982, pp. 466-470, Vol. 106, No. 2.	
	R41	DE COSA, B. <i>et al.</i> "Overexpression of the <i>Bt cry2 Aa2</i> operon in chloroplasts leads to formation of insecticidal crystals" <i>Nature Biotechnology</i> , January 2001, pp. 71-74, Vol. 19.	
	R42	DE GRAY, G. <i>et al.</i> "Expression of an Antimicrobial Peptide via the Chloroplast Genome to Control Phytopathogenic Bacteria and Fungi" <i>Plant Physiology</i> , November 2001, pp. 852-862, Vol. 127.	
	R43	DIXON, T. C. <i>et al.</i> "Anthrax" <i>The New England Journal of Medicine</i> , September 9, 1999, pp. 815-826, Vol. 341, No. 11.	
	R44	DRUM, C. L. <i>et al.</i> "Structural basis for the activation of anthrax adenylyl cyclase extoxin by calmodulin" <i>Nature</i> , January 24, 2002, pp. 396-402, Vol. 415.	
	R45	EDWARDS, K. <i>et al.</i> "A simple and rapid method for the preparation of plant genomic DNA for PCR analysis" <i>Nucleic Acids Research</i> , January 2, 1991, pp. 1349, Vol. 19, No. 6.	
	R46	EYLES, J. E. <i>et al.</i> "Analysis of local and systemic immunological responses after intra-tracheal, intra-nasal and intra-muscular administration of microsphere co-encapsulated <i>Yersinia pestis</i> sub-unit vaccines" <i>Vaccine</i> , 1998, pp. 2000-2009, Vol. 16, No. 20.	
	R47	EYLES, J. E. <i>et al.</i> "Generation of protective immune responses to plague by mucosal administration of microsphere coencapsulated recombinant subunits" <i>Journal of Controlled Release</i> , 2000, pp. 191-200, Vol. 63.	
	R48	FANG, Y.D. <i>et al.</i> "Agrobacterium-mediated barley ( <i>Hordeum vulgare</i> L.) transformation using green fluorescent protein as a visual marker and sequence analysis of the T-DNA: barley genomic DNA junctions", <i>J. Plant Physiol.</i> , 2002, pp.1131-1138, Vol. 159.	

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			First Named Inventor	Henry Daniell	
			Group Art Unit	1638	
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Sheet	6	of	12	Attorney Docket Number	CHL-T107C3Z1

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	R74	MASON H. S. <i>et al.</i> "Edible vaccine protects mice against <i>Escherichia coli</i> heat-labile enterotoxin (LT): potatoes expressing a synthetic LT-B gene" <i>Vaccine</i> , 1998, pp. 1336-1343, Vol. 16, No. 13.	
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	R109	TITBALL, R. W. <i>et al.</i> "Vaccination against bubonic and pneumonic plague" <i>Vaccine</i> , 2001, pp. 4175-4184, Vol. 19.	
	R110	TUBOLY, T. <i>et al.</i> "Immunogenicity of porcupine transmissible gastroenteritis virus spike protein expressed in plants" <i>Vaccine</i> , 2000, pp. 2023-2028, Vol. 18.	
	R111	TUMPEY, T. M. <i>et al.</i> "Mucosal Delivery of Inactivated Influenza Vaccine Induces B-Cell-Dependent Heterosubtypic Cross-Protection against Lethal Influenza A H5N1 Virus Infection" <i>Journal of Virology</i> , June 2001, pp. 5141-5150, Vol. 75, No. 11.	
	R112	VARSHNEY, A. <i>et al.</i> "Stable transformation and tissue culture response in current European winter wheat germplasm" <i>Mol. Breeding</i> , 2001, pp. 295-309, Vol. 8.	
	R113	VASIL, I. K. <i>et al.</i> "Evaluation of baking properties and gluten protein composition of field grown transgenic wheat lines expressing high molecular weight glutenin gene 1Ax1" <i>J. Plant Physiol</i> 2001, pp. 521-528, Vol. 158.	
	R114	WALMSLEY, A. M. <i>et al.</i> "Plants for delivery of edible vaccines" <i>Curr. Opin. Biotechnol.</i> April 2000, pp. 126-129, Vol. 11, No. 2.	
	R115	WESCHE, J. <i>et al.</i> "Characterization of Membrane Translocation by Anthrax Protective Antigen", <i>Biochemistry</i> , 1998, pp. 15737-15746, Vol. 37.	
	R116	WILLIAMSON, E. <i>et al.</i> "Modulating Dendritic Cells to Optimize Mucosal Immunization Protocols" <i>Journal of Immunology</i> , 1999, pp. 3668-3675, Vol. 163.	
	R117	WILLIAMSON, E. D. <i>et al.</i> "A sub-unit vaccine elicits IgG in serum, spleen cell cultures and bronchial washings and protects immunized animals against pneumonic plague" <i>Vaccine</i> , 1997, pp. 1079-1084, Vol. 15, No. 10.	
	R118	WILLIAMSON, E. D. <i>et al.</i> "A single dose sub-unit vaccine protects against pneumonic plague" <i>Vaccine</i> , 2001, pp. 566-571, Vol. 19.	
	R119	WILLIAMSON, E. D. <i>et al.</i> "An IgG1 titre to the F1 and V antigens with protection against plague in the mouse model" <i>Clin. Exp. Immunol.</i> , 1999, pp. 107-114, Vol. 116.	
	R120	WILLIAMSON, E. D. "Plague vaccine research and development" <i>Journal of Applied Microbiology</i> , 2001, pp. 606-608, Vol. 91.	

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/500,351	
			Filing Date	June 25, 2004	
			First Named Inventor	Henry Daniell	
			Group Art Unit	1638	
			Examiner Name		
Sheet	12	of	12	Attorney Docket Number	CHL-T107C3Z1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R121	XU, J. <i>et al.</i> "Dissection of RNA-mediated ryegrass mosaic virus resistance in fertile transgenic perennial ryegrass ( <i>Lolium perenne</i> L.)" <i>The Plant Journal</i> , 2001, pp. 265-274, Vol. 26, No. 3.	
	R122	YE, G. N. <i>et al.</i> "Optimization of delivery of foreign DNA into higher-plant chloroplasts" <i>Plant Mol. Biol.</i> , December 1990, pp. 809-819, Vol. 15, No. 6.	
	R123	YU, J. <i>et al.</i> "A plant-based multicomponent vaccine protects mice from enteric diseases" <i>Nature Biotechnology</i> , June 2001, pp. 548-552, Vol. 19.	
	R124	YUAN, L. <i>et al.</i> "Intranasal Administration of 2/6-Rotavirus-Like Particles with Mutant <i>Escherichia coli</i> Heat-Labile Toxin (LT-R192G) Induces Antibody-Secreting Cell Responses but Not Protective Immunity in Gnotobiotic Pigs" <i>Journal of Virology</i> , October 2000, pp. 8843-8853, Vol. 74, No. 19.	
	R125		
	R126		
	R127		
	R128		
	R129		
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